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10/521,925	08/16/2005	Yoshinori Sato	NAGACO1.001APC	6147

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EXAMINER

GWARTNEY, ELIZABETH A

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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12/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/521,925	Applicant(s) SATO ET AL.	
	Examiner Elizabeth Gwartney	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-12, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 5 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Amendment filed 09/12/2008 has been entered. Claim 6 has been cancelled and claims 1 and 10 have been amended. Claims 1-5 and 7-15 are pending.

Claim Objections

2. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim given that Tg of claim 3 is broader than that of claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4 and 12, the term “virtually” renders the claim indefinite. It is unclear what is encompassed by a lactic acid polymer that is "virtually" a poly-L-lactic acid polymer. Does applicant mean containing no other lactic acid polymer than poly-L-lactic acid?

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 7-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 00/19837).

Regarding claim 1, Li discloses a gum base composition comprising biodegradable ingredients, wherein said biodegradable ingredients include a lactic acid polymer comprising poly-L-lactic acid (see poly D,L-lactic acid and poly D,L-lactic acid -co-glycolic acid - Abstract, p.6/L24-25) having a glass transition temperature of about 50°C (p.6/L19-20) in an amount of 35.7 grams (i.e. about 37% by weight, Example 21 – Preparation of Chewing Gum Base, p. 17/L1-12), and an emulsifying plasticizer in an amount of 14.3 grams (i.e. about 15% by weight,

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see triacetin – Example 1, p. 13/L31-p.14/L4, Example 21 – Preparation of Chewing Gum Base, p. 17/L1-12).

While Li discloses a poly (D,L-lactic acid) having a glass transition temperature of about 50°C (Abstract, p.6/L19-20), Li fails to disclose a gum composition which contains lactic acid polymers having a glass transition temperature of 55°C to 80°C. However, Li discloses that poly (L-lactic acid) polymer is highly crystalline and has a high glass transition temperature (T_g) (p.6/L12, 17-18). Li discloses that when D-lactic acid is copolymerized with L-lactic acid, the resulting copolymers are less crystalline and have a lower T_g (p.6/L14-15, 18-20). Further, Li discloses that poly (D,L-lactic acid) polymer degrades faster than poly (L-lactic acid) polymer (p.6/L22-23). As degradation is a variable that can be modified, among others, by adjusting the D-lactic acid monomer ratio in poly (D,L-lactic acid) polymer, it would have been obvious to one of ordinary skill in the art at the time of the invention to reduced the amount of D-lactic acid monomer in the poly (D,L-lactic acid) used in the gum base of Li, to increase both T_g and crystallinity and thus decreasing the rate the gum base degrades. Further, by doing so, the gum will last longer while being chewed.

Regarding claim 2, Li discloses all of the claim limitations as set forth above. Further, Li discloses that the content of said lactic acid polymer is from 10% by weight to less than 50% by weight (see Example 22 – Preparation of Chewing Gum Base, p. 17/L1-12).

Regarding claim 3, Li discloses all of the claim limitations as set forth above. Li also discloses the gum composition wherein said lactic acid polymer has a glass transition temperature of about 50°C (p.6/L19-20)) and a crystallinity of less than 18% (p.3/L13-14). While Li does not disclose said lactic acid polymer has a weight average molecular weight of

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50,000 to 200,000, the reference does disclose a weight average molecular weight of approximately 10,000 to about 500,000 g/mol (p.3/L5-6). It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness. *In re Malagari*, 182 USPQ 549.

Regarding claim 4, Li discloses all of the claim limitations as set forth above and a gum base wherein said lactic acid polymer is virtually a poly-L-lactic acid polymer (*see* poly (D,L-lactic acid) may have a D-isomer content from approximately 5% to about 95ml% - p.7/L9-11).

Regarding claim 7, Li discloses all of the claim limitations as set forth above a gum base composition which contains an acetylated monoglyceride as said emulsifying plasticizer (p.9/L8).

Regarding claim 8, Li discloses all of the claim limitations as set forth above. While Li does not disclose that the ratio by weight of said lactic acid polymer to said emulsifying plasticizer is from 90:10 to 80:20, the reference discloses that poly (D,L-lactic acid) can be softened (i.e. change elasticity) by a number of plasticizers (p.5/L6-9). Thus, the elasticity of the lactic acid polymer at room temperature is a variable that can be modified, among others, by varying the ratio by weight lactic acid polymer to emulsifying plasticizer and therefore, the ratio by weight lactic acid polymer to emulsifying plasticizer would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the heater diameters cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the heater diameters in the apparatus of Takada et al. to

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obtain the desired heat capacity (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 9, Li discloses all of the claim limitations as set forth above and a gum base wherein all ingredients of said composition are biologically degradable (p.4/L29-31).

Regarding claim 10, Li discloses a method of producing a gum base composition comprising biodegradable ingredients (p.4/L29-31), which comprises steps of heat kneading and softening poly-L-lactic acid (see poly D,L-lactic acid and poly D,L-lactic acid -co-glycolic acid - Abstract, p.6/L24-25) having a glass transition temperature of about 50°C (p.6/L19-20) in a pressure kneader (*see* sigma blade mixer - p. 10/L9-10), and homogenizing the resulting softened lactic acid polymer by adding an emulsifying plasticizer to it (*see* triacetin - Example 21), said biodegradable ingredients containing lactic acid polymers in an amount of 35.7 grams (i.e. about 37% by weight, Example 21-Preparation of Chewing Gum Base, p. 17/L1-12).

While Li discloses a poly (D,L-lactic acid) having a glass transition temperature of about 50°C (Abstract, p.6/L19-20), Li fails to disclose a gum composition which contains lactic acid polymers having a glass transition temperature of 55°C to 80°C. However, Li discloses that poly (L-lactic acid) polymer is highly crystalline and has a high glass transition temperature (T_g) (p.6/L12, 17-18). Li discloses that when D-lactic acid is copolymerized with L-lactic acid, the resulting copolymers are less crystalline and have a lower T_g (p.6/L14-15, 18-20). Further, Li discloses that poly (D,L-lactic acid) polymer degrades faster than poly (L-lactic acid) polymer (p.6/L22-23). As degradation is a variable that can be modified, among others, by adjusting the

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D-lactic acid monomer ratio in poly (D,L-lactic acid) polymer, it would have been obvious to one of ordinary skill in the art at the time of the invention to have reduced the amount of D-lactic acid monomer in the poly (D,L-lactic acid) used in the gum base of Li, to increase both Tg and crystallinity and thus decreasing the rate the gum base degrades. Further, by doing so, the gum will last longer while being chewed.

Regarding claim 11, Li discloses all of the claim limitations as set forth above. While Li discloses heating kneading a lactic acid polymer to between 50°C and 130°C (p.11/L8), the reference does not explicitly disclose that the temperature of said pressure kneader is 120°C to 130°C. However, it would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness. *In re Malagari*, 182 USPQ 549.

Regarding claim 12, Li discloses all of the claim limitations as set forth above. Further, Li discloses a gum base wherein said lactic acid polymer is virtually a poly-L-lactic acid polymer (see poly (D,L- lactic acid) may have a D-isomer content from approximately 5% to about 95ml% - p.7/L9-11).

Regarding claim 14, Li discloses all of the claim limitations as set forth above and gum base composition which contains an acetylated monoglycerides as said emulsifying plasticizer (p.9/L8).

Regarding claim 15, Li discloses all of the claim limitations as set forth above. While Li does not disclose that the ratio by weight of said lactic acid polymer to said emulsifying plasticizer is from 90:10 to 80:20, the reference discloses that poly (D,L-lactic acid) can be

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softened (i.e. change elasticity) by a number of plasticizers (p.5/L6-9). Thus, the elasticity of the lactic acid polymer at room temperature is a variable that can be modified, among others, by varying the ratio by weight lactic acid polymer to emulsifying plasticizer and therefore, the ratio by weight lactic acid polymer to emulsifying plasticizer would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the ratio of lactic acid polymer to emulsifying plasticizer cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the ratio by weight lactic acid polymer to emulsifying plasticizer in the chewing gum of Li to obtain the desired elasticity (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Allowable Subject Matter

9. Claims 5 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: Li does not disclose a chewing gum base that contains no other lactic acid polymer other than a poly-L-lactic acid polymer. In fact, Li teaches away from making a chewing gum with a lactic acid polymer comprising pure poly-L-lactic acid because poly-L-lactic acid has a high glass transition temperature (T_g) making it rigid at room temperature and not suitable as a chewing gum masticatory ingredient.

Response to Arguments

11. Applicant's arguments filed 09/12/2008 have been fully considered but they are not persuasive.

Applicants note that Examiner acknowledges Li does not disclose a gum base composition comprising a lactic acid polymer having a Tg of 55°C to 80°C. Therefore, applicants argue that Li does not anticipate amended Claims 1 and 10.

Applicants' arguments with respect to claims 1 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that without the benefit of Applicant's disclosure, there would be no reason for one skilled in the art to modify the disclosure of Li in order to obtain a gum base composition comprising "lactic acid polymers having a glass transition temperature (Tg) of 55°C to 80°C" as recited in amended claims 1 and 10.

Examiner finds that one skilled in the art would be motivated to modify Li based on Li's disclosure. Li states "[i]t has also been found that poly-D,L-lactic acid degrades much faster than crystalline PLLA." Based on this knowledge, one of ordinary skill in the art at the time of the invention would have been motivated to modify the teachings of Li by using a more crystalline polymer (i.e. polymer with higher Tg) for the purpose of making a chewing gum that degrades slower and lasts longer while chewing.

Applicants argue that Li teaches away from use of lactic acid polymers having a higher Tg in a chewing gum composition. Li states "[s]ince the common form, PLLA [poly]L-lactic acid], is highly crystalline and has a glass transition temperature (Tg) around 58°C, it is rigid at room temperature and, not suitable as a chewing gum masticatory ingredient. Applicants find

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that based on the teaching of Li, one of skill in the art would not have used lactic acid polymers having a Tg of higher than about 50°C.

Examiner finds that while Li teaches the negative properties of pure crystalline PLLA in chewing gum, the reference also teaches that poly-D,L-lactic acid degrades much faster than crystalline PLLA. One skilled in the art would have been motivated to alter the properties of poly-D,L-lactic acid to obtain a chewing gum with a slower rate of disintegration. One would alter the crystallinity and Tg by adjusting the amount of poly-D-lactic acid in the poly-D,L lactic acid polymer. Further, it is not the examiner's position to use PLLA but rather to reduce the amount of D-lactic acid in poly-D,L-lactic acid to alter the crystallinity and Tg to values, including those presently claimed, and obtain gum with slower rate of disintegration.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794